Manufactured by SD BIOSENSOR

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STANDARD™ F100

Thank you for your purchase of the STANDARD F100 Analyzer.

This user manual contains all the information needed to use the analyzer and keep it ready to operate. Please read this user manual carefully before using the analyzer. Familiarize yourself with the required preparations and the measurement procedure before performing the first measurement. Also read the package inserts of the test strips to be used for the planned test.

If you have any questions about the analyzer, please contact your healthcare professional or local distributor. You can also visit www.sdbiosensor.com for product demonstrations.

Thank you again for choosing the STANDARD F100 analyzer.

STANDARD™

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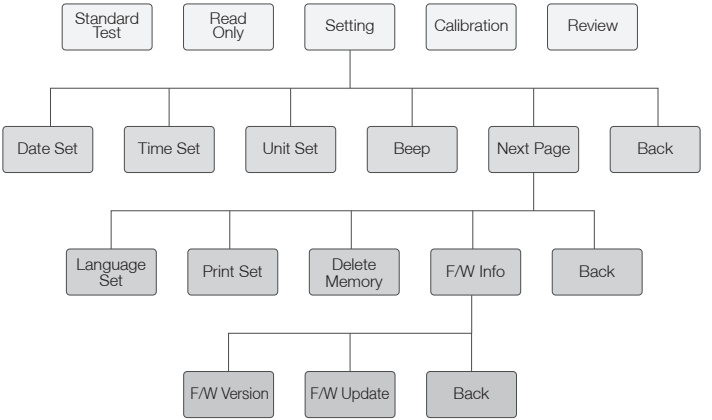
CHAPTER 01. General Information

Main Menu Structure



Symbol

The packaging materials, labels and instruction for use for STANDARD F100 analyzer may contain the following symbols or abbreviations which are listed below with their meaning.

Symbol	Description
	Manufacturer
	*In vitro* diagnostic medical device Intended to use outside the body.
	Consult instructions for use
	Reference number
	Date of manufacture Indicate the date of manufacture for this analyzer
	Serial number for this analyzer
	Note
	Indicate that the product is fragile and you need to handle it with care
	Batch code Indicate the lot number for this system
	Crossed out wheeled bin Discard it separately from other household waste
	Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices
	Indicate that you should keep the product dry
	Caution! Indicate a situation, which if not avoided could result in damage to the device or incorrect results.
	Potential Biohazard!

Brief Precautions and Limitations


Caution

- For *in vitro* diagnostic use.
- Always operate the STANDARD F100 analyzer on a surface that is level and dry and not in direct sunlight.
- STANDARD F100 analyzer has internal correction for normal levels of ambient light, but highly intense light falling into the analyzer may cause serious interference with the measurement and must be avoided.
- Never move the analyzer while there is a test in progress.
- Do not drop the analyzer as it could damage the unit.
- Do not attempt to open or disassemble the analyzer.
- Do not immerse in water or cleaning solutions.
- Dispose of the battery and accessories in accordance with local guidelines.

To reduce the risk of incorrect results

- The STANDARD F100 analyzer should be used by trained operators.
- Do not use if the analyzer is reporting an error condition that cannot be corrected.
- To obtain accurate results, refer to the assay-specific package insert for details on specific tests.
- Use the test kit within the expiration dating.


Potential Biohazard!

To reduce the risk of biohazard

- Dispose of used specimens in accordance with federal, state and local requirements.
- Treat specimens and patient samples as potentially biohazardous material.
- Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
- Use of nitrile, latex, or other gloves is recommended when handling patient samples.

CHAPTER 02. Introduction

Intended Use: Purpose of the Analyzer

The STANDARD F100 analyzer works to measure the quantitative or qualitative measurement of body fluid such as blood, urine, nasal mucus, and so on. The analyzer is indicated for monitoring or diagnosing the body fluid parameter. The STANDARD F100 analyzer should be used with the specified test strips. This analyzer is indicated in clinical settings by healthcare professionals. The STANDARD F100 analyzer intended to be used with the specific test strip manufactured by SD BIOSENSOR, Inc.

Product Description

The STANDARD F100 analyzer is an optoelectronic instrument that uses a reflectance-based measurement method to evaluate the line signal (fluorescent or visible ray) intensities on the assay test strip, and a specific algorithm to determine the quantitative or qualitative results of any target analyte(s). The analyzer then displays the test results to the user in the screen. The result can also be automatically printed through an external printer if it has connected to the analyzer.

Before You Start Testing

Note

Carefully read and follow the instructions in the user manual and package inserts for the test strips and control solutions. It is very important to follow the instructions in order to prevent an incorrect result or improper treatment.
Before use, please check the latest version of software from your distributor and head office. Then update and start measuring.

Samples
The STANDARD F100 analyzer should be only used the specific test strips for STANDARD F100 analyzer. Because samples are quite different to the test strip's parameter, follow the instruction from the reference of the test strip's manual.

Safety information
There is a potential risk of infection. We recommend that healthcare professionals using the STANDARD F100 analyzer to perform measurements for more than one patient use gloves and follow all other locally applicable health and safety regulations.

Operating conditions

To ensure proper function of your STANDARD F100 analyzer, observe the following guidelines.

- The STANDARD F100 analyzer is only for interior use.
- Operate the analyzer only within the acceptable environmental conditions; temperature: 0-50°C, humidity: 10-93%.
- In order to perform a measurement, place the analyzer on a level surface or hold it in your hand.
- Strong electromagnetic fields may impair the function of the analyzer. Do not use the analyzer close to sources of strong electromagnetic radiation.
- The analyzer's air vents must be free for air. (Do not cover the air vents.)
- If the analyzer cause a sudden malfunction, unplug the AC adapter from the outlet.

System Components

Inspect the shipping container for obvious shipping damage prior to opening. Unpack the shipping container and inspect the unit and components for damage.

STANDARD F100 Analyzer

Specification

Analyzer	STANDARD F100 analyzer
Power Supply	Input: AC 100~240 V, 50/60 Hz (Voltage tolerance ± 10 %) Output: DC 5V/2A
Power Consumption	Max 5W
Over Voltage Category	II
Pollution Degree	II
Labeling	User Manual, Quick Guide
Rating Power Supply	DC 5 V

Accessories of the STANDARD F100 Analyzer

	Item	Details
Accessory	STANDARD F Calibration Set	F CAL-1, F CAL-2, F CAL-3
	Batteries	4 Batteries (1.5 V, AA)
Optional	STANDARD F Test Device	Specific test device manufactured by SD Biosensor, Inc.
	Barcode scanner	USB Barcode scanner
	STANDARD Printer	Portable printer
	Printer paper	
	AC/DC Power Adaptor	Input: AC 100~240 V, 50/60 Hz (Voltage tolerance ± 10 %) Output: DC 5V/2A
	BT Dongle	

With a BT Dongle connection, checking test results in mobile application and using a wireless printer are available.

Overview of F100 Analyzer

A. Left Button : Use for moving cursor or exit test mode
B. Center (Enter) Button : Use for power on/off or menu selection
C. LCD Display
D. Right Button : Use for moving cursor
E. Strip Slot : Part for inserting a test strip to analyzer

F. PC Communication Port : Use for downloading test results to a personal computer. (if you have software) or use for upgrading analyzer's software

G. Printer Port, Additional Port : Print test results to external thermal printer (If you have STANDARD thermal printer)

H. Battery Compartment Lid : Provide access to the battery compartment (4 AA 1.5V alkaline batteries)

I. DC Jack Port : Connect power supply adapter 5V/2A

STANDARD F100 Display

	Battery level		Beep ON
	AC adapter in		Test strip
	Printing		External device
	Desktop		Control solution
	Sample		Processing
	Expired date		Temperature
	Test strip's barcode		

Power Supply

5V/2A AC/DC power adapter or 4 AA alkaline batteries can be used.
When using batteries, to save power, the analyzer turns itself off after 1 minutes unless a button is pressed or a new test strip is inserted. When the analyzer turns itself off, all test results obtained so far remain in the memory. With a set of fresh batteries, you will normally be able to perform at least 50 measurements. When the low battery (empty display) warning is displayed, approximately 10 measurements can still be performed. In this case, replace the batteries as soon as possible.

CHAPTER 03. Setting and Performing

Operating the Analyzer

Before using the analyzer, check the following steps as a priority.

5V/2A AC/DC power adapter or 4 AA alkaline batteries can be used for STANDARD F100 analyzer.

STEP 1-1. Insert batteries

The requested batteries are 1.5V AA-sized alkaline manganese batteries. To avoid the risk of trouble, do not use rechargeable batteries in the STANDARD F100 analyzer.

1. Open the battery lid by slightly pressing the cover towards the center of the analyzer.
2. Remove the battery lid from the analyzer.
3. Insert four batteries into the compartment according to the illustrations. Please set the batteries with correct polarity orientation. “+” (battery head) and “–” (terminals).
4. Close the battery lid.
5. Turn the analyzer if batteries work properly or not.
6. Check the function of display to prevent misinterpretations.

Note

- If the display screen does not function for a long time, you can press the center button for few seconds (the next time you switch on the analyzer). The display screen is then shown for the time when you press the button.
- After replacing the batteries, verify that the time and date are correct. If they are not, reset the analyzer.
- Because batteries with different capacities can induce the malfunction of the analyzer, replace all four batteries at the same time.

STEP 1-2. Connect AC/DC adapter jack

1. SD BIOSENSOR doesn't provide adopter. (You can use AC/DC adapter jack that is 4 mm external-diameter and 1.7 mm internal-diameter, and output is 5V/2A.)
2. Connect AC/DC adapter jack to the DC jack port at the back of analyzer.
3. The adopter must compliance with EN ISO 61010.

Note

If the batteries are already inserted and then DC adapter jack is connected, the analyzer use a power only from AC/DC jack.

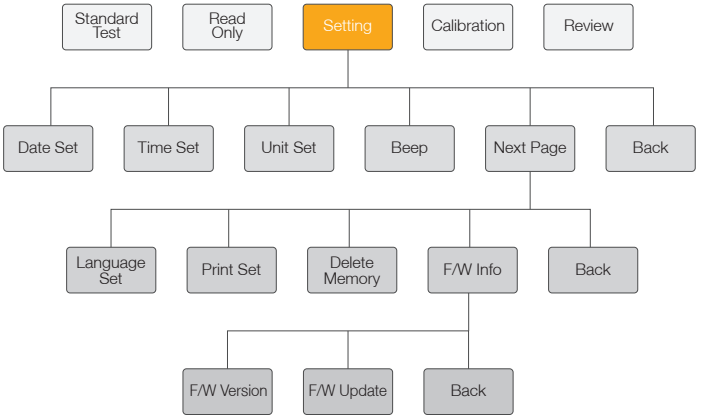
Set the Analyzer

Brief overview of the analyzer settings

Stage	Setting	Detailed Setting	Default Setting
1	Date Set	Format: mm-dd/dd-mm Year/Month/Day	Current Date
2	Time Set	Format: 24h-12h Hour/Minute/Second	24h/Current Time
3	Unit Set	HbA1c	NGSP %
4	Beep Set	On Off	On
5	Language Set	English Chinese	English
6	Print Set	Auto Print: On / Off Copies 1 / 2	Auto Print On/Copies 1
7	Delete Memory	Delete all memory	-
8	F/W Info	F/W Version F/W Update	Current F/W Information

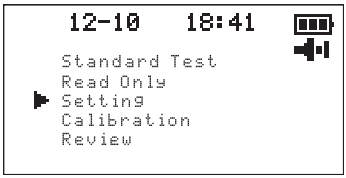
* The new analyzer is set-up with "Default setting" format.

Entering set mode

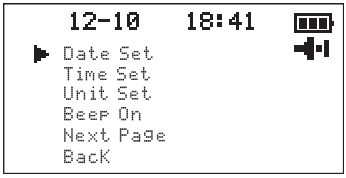


1. If you want to enter the setting mode, press the ◄ or ► button to move the cursor.
2. To select the setting mode or turn on/off the analyzer, press the center button.
3. If you select the 'Setting', total 8 menu will be displayed.
4. The setting procedure can be terminated at any time by pressing the Back button.

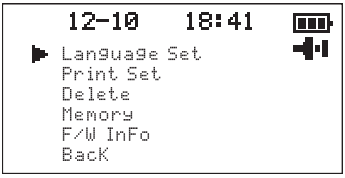
Left button	Center button	Right button
◄	OK	►
Move cursor	Select	Move cursor



Main Menu



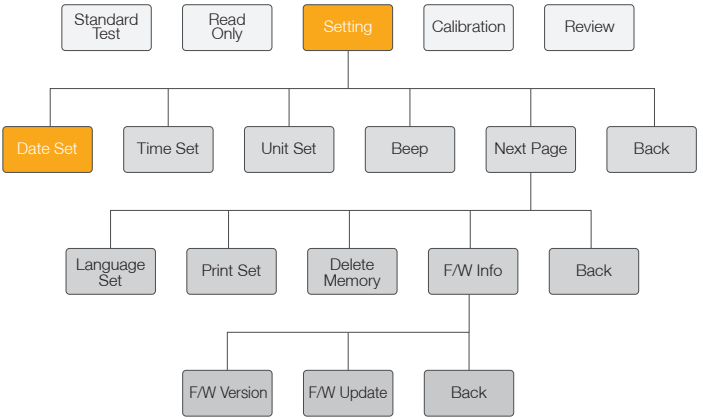
Date Setting Menu



Language Setting Menu

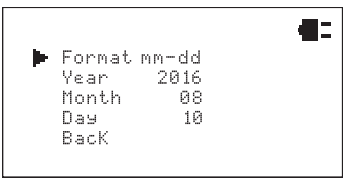
Date Set

At 1st stage, set the date.



The first menu is 'Date Set'. In the Setting Menu, select the 'Date Set' to change the present date. You can set up the year, month, day, and month-day or day-month format.

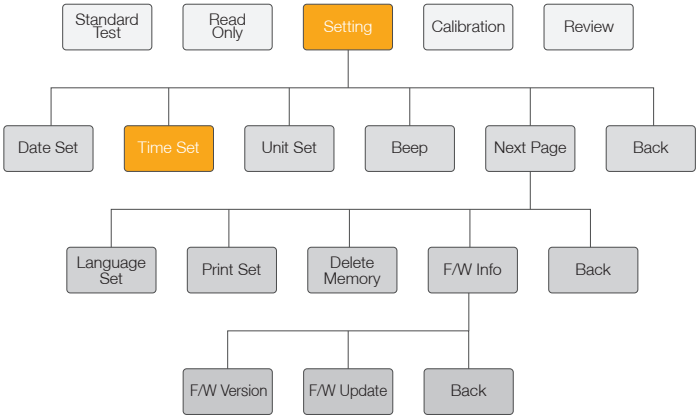
Left button	Center button	Right button
◄	OK	►
Move cursor	Select	Move cursor



Default Setting: mm-dd, current date

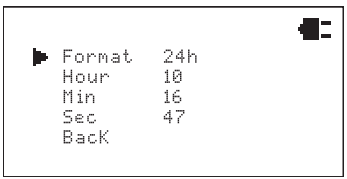
Time Set

At 2nd stage, set the time.



The second menu is 'Time Set'. You can set up the hour, minute, second, and 12h or 24h time format. After choosing the 12h or 24h format, you can press the button to update the current time.

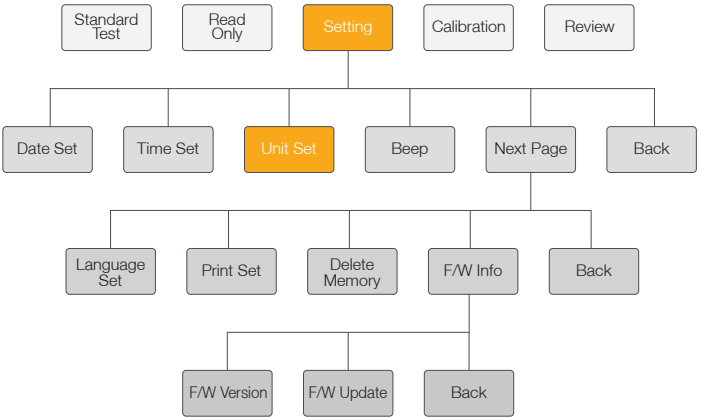
Left button	Center button	Right button
◄	OK ⏻	►
Move cursor	Select	Move cursor



Default Setting: 24h/Current time

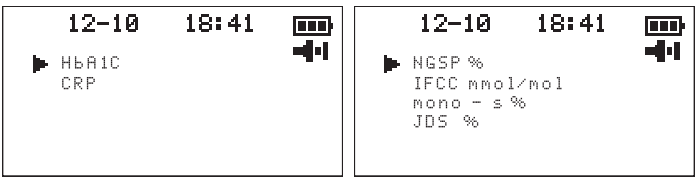
Unit Set

At 3rd stage, set the unit.



The third menu is 'Unit Set'. Unit set is only for quantitative analysis STANDARD F100 analyzer applies corresponding unit. When you carry out the quantitative analysis of sample, STANDARD F100 analyzer applies corresponding unit. The parameters can be increased by update of analyzer software.

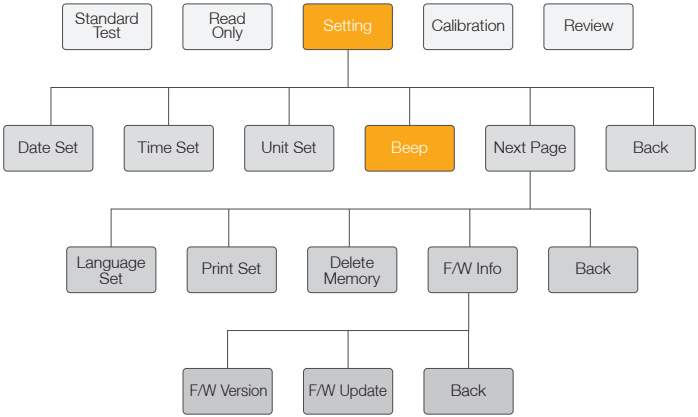
Left button	Center button	Right button
◄	OK ⏻	►
Move cursor	Select	Move cursor



Ex : HbA1c

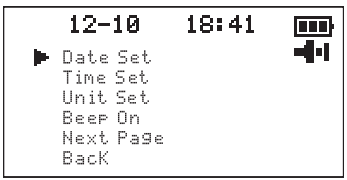
Beep Set

At 4th stage, set the beep – ON / OFF.



The fourth menu is 'Beep'. The default setting is 'ON' mode. If you want to turn on the beep, select the 'Beep ON' mode. Otherwise, you should change the mode to 'Beep OFF'.

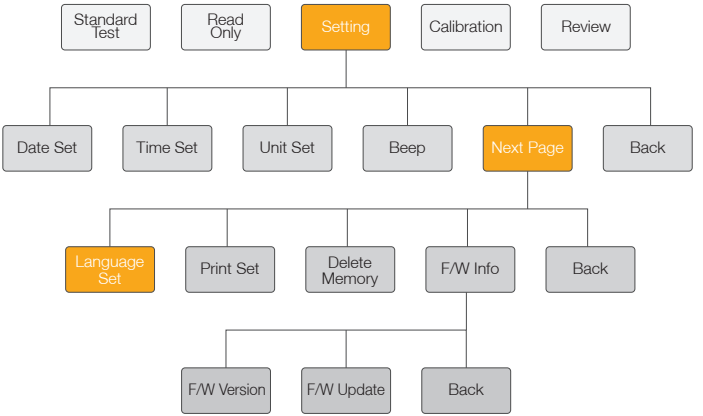
Left button	Center button	Right button
◄	OK	►
Move cursor	Select	Move cursor



Default Setting: ON

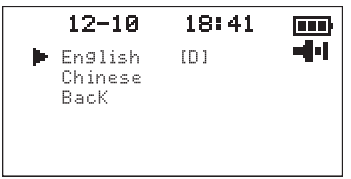
Language Set

At 5th stage, set the language.



The fifth menu is 'Language Set'. From the setting menu, select the 'Language Set'. You can set up the English or Chinese format in order.

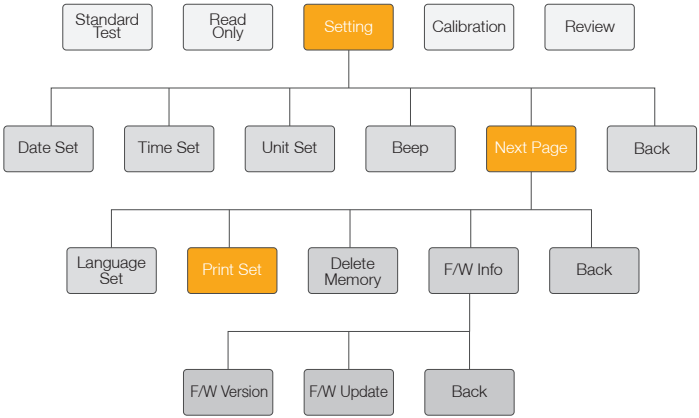
Left button	Center button	Right button
◄	OK	►
Move cursor	Select	Move cursor



Default Setting: English

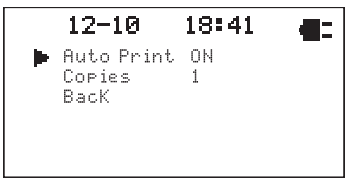
Print Set

At 6th stage, set the print function – ON / OFF.



The sixth menu is 'Print Set'. At this mode, you can set up the print mode. If you want to print automatically, select the 'Auto Print ON' mode. Otherwise, you should change the mode to 'Auto Print OFF'. Then, set the number of copies as you please.

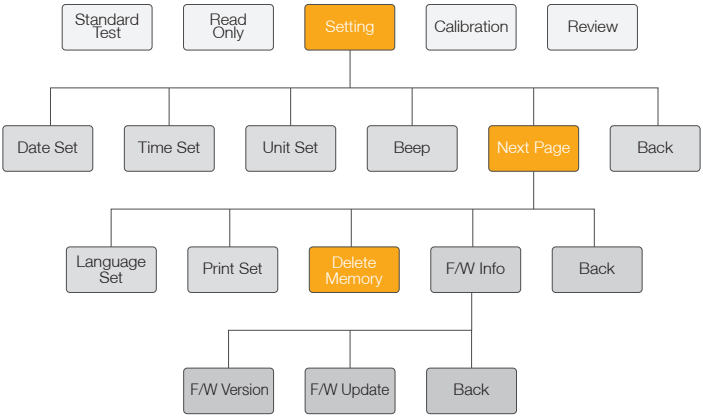
Left button	Center button	Right button
◄	OK ⏻	►
Move cursor	Select	Move cursor



Default Setting: Auto Print ON, Number of Copies 1

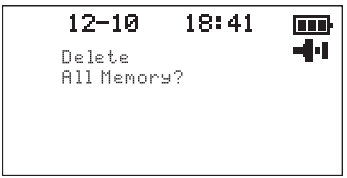
Delete Memory

In 7th stage, set the delete memory mode.



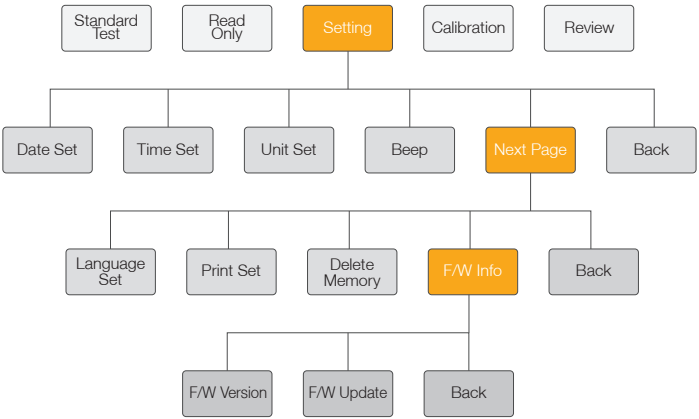
The seventh menu is 'Delete Memory'. At this mode, you can choose if the saved memories are deleted or not. When you want to delete all saved data, select the delete function.

Left button	Center button	Right button
◄	OK	►
Move cursor	Select	Move cursor



F/W Info

At 8th stage, check the F/W information.



The eighth menu is 'F/W Info'. You can verify the F/W information such as F/W version and F/W update.

FIRMWARE UPDATE PROCEDURE

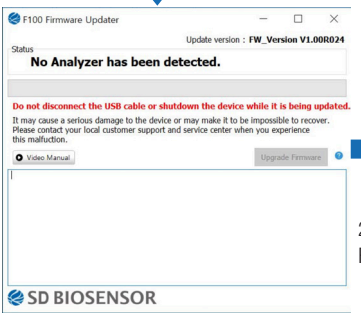
PROCEDURE FOR THE COMPUTER	PROCEDURE FOR THE F100

0. Be sure connect the power cable to STANDARD F100 analyzer before updating the software.

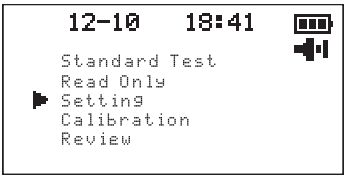
<Connect the power cable to the STANDARD F100 Analyzer>

1. Run firmware update program 'F100FirmwareUpdater_VxxxRxxx.exe'.

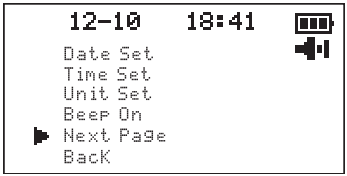
F100FirmwareUpdater_v100R024.exe



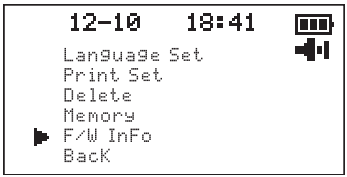
2. Select Setting button on the F100 LCD screen.



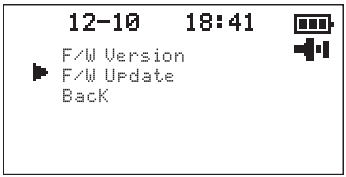
<Select the 'Supervisor'>



<Select the 'Next Page'>



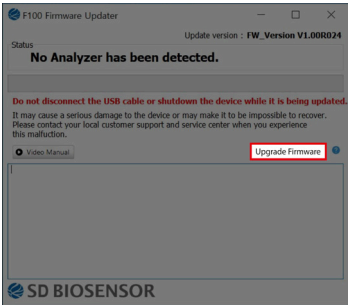
<Select the 'F/W Info'>



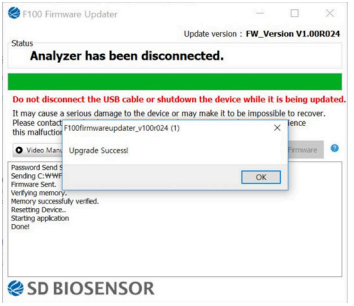
<Select the 'F/W Update'>

Please connect the Mini-5pin USB cable in this step, otherwise 'Firmware Upgrade' button won't be activated.

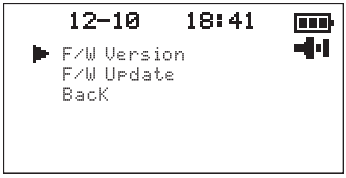
<Connect 'Mini-5pin USB cable' to computer and F100 Analyzer>



<Push the 'Upgrade Firmware' button once it is activated>



Left button	Center button	Right button
◄	OK	►
Move cursor	Select	Move cursor

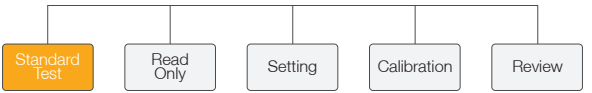


Default Setting: Current F/W Information

Performing a Measurement

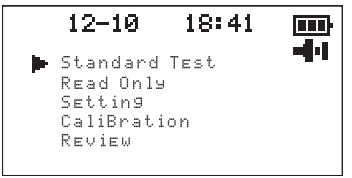
Caution

Refer to the insert corresponding to specific parameters.



Select the desired test mode

Standard Test mode may be most convenient for reading a single patient sample, as the user can standard test during the development period. **Read Only** mode may be most convenient for analysis of large volume as STANDARDF100 analyzer can quickly read multiple patient samples sequentially.



Note

Analyzer can memorize the latest test mode. When you turn on the analyzer, previous ongoing test mode will be displayed on screen.

Press start button

Press the **center button**(**OK**) to **start** and progress after each test preparation.

Patient test results

When the test is complete, the results for the patient specimen test(s) will be displayed on the analyzer screen.

The result can also be automatically printed through an STANDARD thermal printer if it has connected to the analyzer.

Refer to the assay-specific package insert for details on how to interpret results for specific tests.

Note

Once results have been generated for an individual test strip, the analyzer would not accept another test strip.

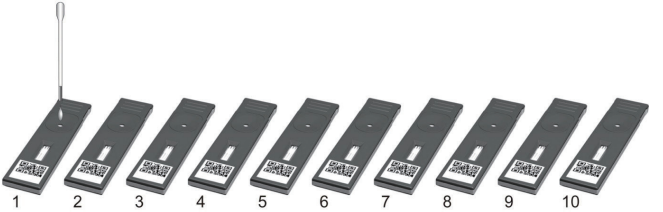
If the procedural control is “Invalid,” re-test the test with a new patient sample and a new test strip.

Standard Test and Read Only Modes

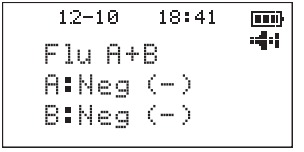
In the **Standard Test** mode, insert test strip into the slot and dispense the patient sample into the strip and press start button. The analysis will be developed automatically for the required time period (pre-programmed for each test), with analyzer scanning the strip, interpreting the data and displaying the test result.

In the **Read Only** mode, dispense the patient sample into the sample well. Measure the development time outside of the analyzer. This can be done on the counter or benchtop using a timer. Refer to the assay-specific package insert for the required development time. Once the development time is complete, insert the test strip into the analyzer. The analyzer will immediately scan and display the test result within 10 seconds (10 sec.).

- When ready to test, prepare strip to receive the specimen immediately before use.
- Label the test strip accordingly and place them in order in the work area.
- Once specimen is prepared, you should proceed the test step.



- Add prepared specimen #1 to the test strip #1, then immediately set your timer to the designated development time as indicated in the assay-specific package insert.
- 1 minute later, add specimen #2 to the test strip #2.
- Continue to add the appropriate prepared specimen to its appropriate test strip at an interval of 1 minute.
- When the timer goes off for test strip #1, then insert test strip #1 into the analyzer, the analyzer will display the result in approximately 10 seconds.



Ex : Influenza

- Remove test strip #1 and insert the test strip #2 into the analyzer and press start button for running test.
- Proceed in the same fashion for all test strip.

CHAPTER 04. Using the Analyzer Memory and Data Transfer

Displaying Stored Measured Values

The STANDARD F100 analyzer saves 1000 results accompanied with measured date and time. If the new result is added into analyzer filled with memories, the analyzer deletes the old data automatically.

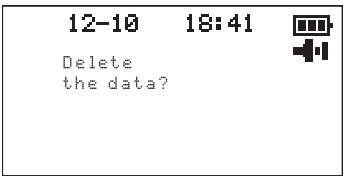
Select the 'Review' mode, then press (◄) or (►)button.

Left button	Center button	Right button
◄	OK ⏻	►
Oldest data will be shown on the display screen.	Exit the current menu on the display screen.	Latest data will be shown on the display screen.

Delete Memory

You can delete unnecessary data for memory review.

To delete the displayed data, press ◄ button and ► button at the same time during two seconds. When the 'Delete the data?' message is shown on the screen, press center button. If you don't want to delete the data at this state, press ◄ button.



Printing

You can print the measured data with external printer system.
1. Connect an external printer with STANDARD F100 analyzer.
2. The printer icon is displayed on the screen.
3. Press center button during 2 seconds at review mode.

Data Transfer

Data can be downloaded from STANDARD F100 analyzer via USB interface.

To get an information of suitable system (PC), please call your local service center.
The STANDARD F100 analyzer shows you the following PC image during the data transfer.

CHAPTER 05. Calibration Set Test

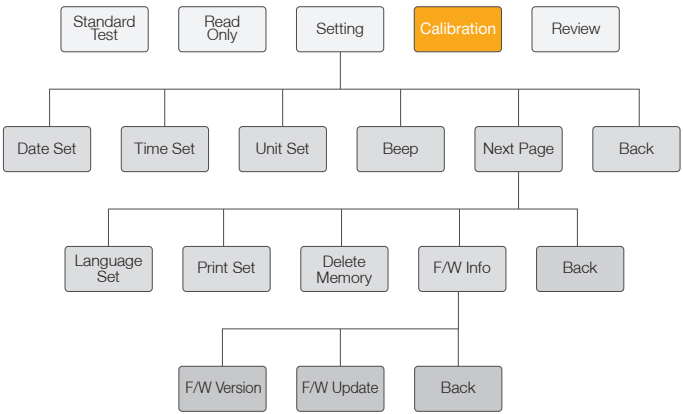
Calibration Set Test

Calibration Set Test is a required function that ensures optimal performance by checking the designated method by SD BIOSENSOR, Inc.

When to use calibration set

- Whenever the analyzer is powered on.
- When you drop the analyzer.
- Whenever you do not agree with your result.
- When you want to check the performance of an analyzer and test strip.

How to use the Calibration Set



Perform the calibration set test procedure

Select the ‘Calibration’ in main menu. Then, Use the specific calibration set included with the analyzer.

Insert the CAL-1 then insert the CAL-2 for UV radiation testing and the CAL-3 RGB-LED testing in order. When you insert the calibration set, the analyzer will read the information though the barcode on the calibration strip and proceedautomatically the UV radiation test or RGB-LED test.

When you change the adaptor or battery, the 'Calibration?' message will be displayed on the screen. Select 'Yes' or 'No'.

Note

- If 'EEE' message displays on the screen, it means that the analyzer has a problem. Call the SD BIOSENSOR Customer Care Service Center or local distributor.
- If Calibration Set Test procedure does not complete successfully, notify the SD BIOSENSOR Customer Care Service Center or local distributor.

CHAPTER 06. Shut down, Cleaning and Maintenance

Shut Down

Turn off the analyzer by pressing the center button. When you press the center button for 2 seconds, 'Power OFF?' message is displayed on the screen. Press the center button to shut down the analyzer. Shutdown is complete when the screen goes dark. If you don't use analyzer for several minutes, the analyzer is powered off automatically.
- Adaptor : 5mins / 10mins (Test strip X / Test strip O)
- Battery : 2mins / 5mins (Test strip X / Test strip O)

Cleaning your Analyzer

To prevent malfunction of the analyzer, keep the test strip port free from blood, moisture or dust. Use lint-free cloths. For cleaning, there are suitable solutions such as mild suds, 70 % ethanol or isopropyl alcohol. At the professional case (e.g. doctor's surgery), a mixture of 1-propanol, 2-propanol and glutaraldehyde (brand name "Bacillol plus") is recommended.


Caution

Do not use an abrasive cloth or antiseptic solution, as these may damage the display screen. Always switch off the analyzer before cleaning it!

Maintenance and Transportation

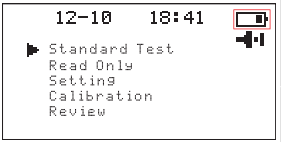
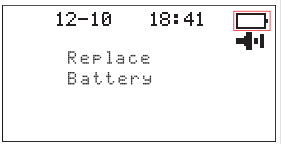
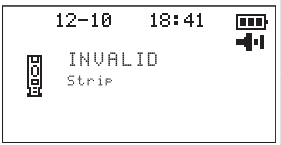
When you turn analyzer on, it automatically tests its own system every time. Then, let you know if something is wrong.


Note

- Keep the test strip slots and internal part of analyzer free from dust.
- The carrying case was designed to store a variety of supplies and protect your analyzer.
- For transporting the analyzer, it needs to be stored at -20 to 50°C (-4 to122°F) and 10% to 93% RH.
- If you keep the analyzer inserted with the battery, keep it at environment of low humidity.

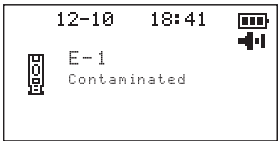
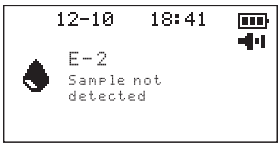
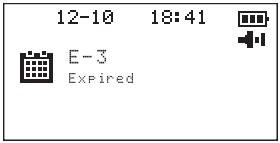
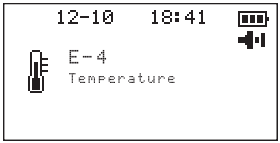
CHAPTER 07. Screen Messages and Troubleshooting

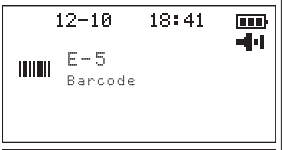
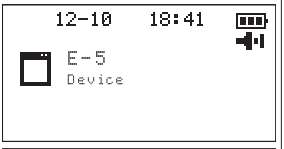
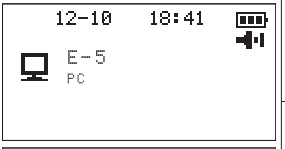
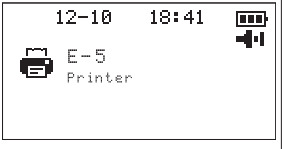
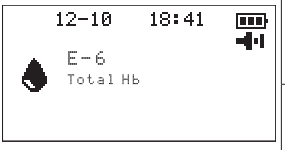
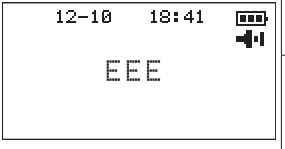
Warning Messages

Indication	Warning description
	**Warning: Low Battery** At this time, battery is getting low but you can still perform about 10 tests. **Solution** Replace the battery as soon as possible.
	**Warning: Replace Battery** Battery power is low. If you press the Enter button after discharging of the battery, the battery icon will flash and then after ten seconds the analyzer will turn off automatically. **Solution** Replace the battery immediately.
	**Warning: Invalid Strip** The strip has extremely low C line. **Solution** Use another test strip.

Error Messages

In certain circumstances error messages may appear on your display. Generally, you should first try the solutions suggested for the respective error. If the problem persists, please contact your local distributor and service center.

Indication	Warning description
	**E-1 - Error: Strip Error** The test strip has been used or is contaminated. **Solution** Discard this test strip and re-test with new strip.
	**E-2 - Error: Extremely Low Sample Error** An insufficient amount of sample was applied. **Solution** Discard this test strip and test again using a new test strip with proper amount of sample.
	**E-3 - Error: Expired Strip** The test strip has passed the expiration date. **Solution** Discard the test strip and re-test with new test strip which is not expired.
	**E-4 - Error: Temperature Error** If the environmental temperature is above or below the operating range of a analyzer, a thermo analyzer icon will appear on the display. **Solution** Move to an area at designated temperature, and run a test. Do not artificially heat or cool the analyzer.

Indication	Warning description
   	**E-5 - Error: Communication Error** The communication between analyzer and Barcode or Device, PC, Printer is failed. **Solution** Connect cable again between analyzer and external device. If the error continues, turn off an analyzer. Then turn on the analyzer again. If there is still error massage, please contact SD BIOSENSOR, Inc.
	**E-6 - Error: Extremely low Total hemoglobin means that the measured total hemoglobin is under 7g/dl.** **Solution** If this error occurs with a sample known to have total hemoglobin in the normal range, turn the analyzer off and back on and re-test. If there is still an error message, please contact SD BIOSENSOR, Inc.
	**EEE - Error: Internal Error to Work** The internal error happened. **Solution** Turn off and then turn on the analyzer again. If there is still error message, please contact SD BIOSENSOR, Inc.

ANNEX 01. Information for Healthcare Professionals

Protection against Infections

There is a potential risk of infection. Medical staff using the STANDARD F100 analyzer to perform measurements for more than one patient must be aware that any object coming into contact with human sample is a potential source of infection.

- Use gloves.
- Apply sample outside the analyzer.
- Follow all other locally applicable guidelines and regulations on health and safety.

REF F100 IVD CE

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